Dear Employee:

Thank you for expressing interest in learning more about Project ImPACT: *Depression,* which is being provided for covered members of the health plan of City of Asheville. Your participation in the program is voluntary and confidential.

Project ImPACT: *Depression* is a joint venture between your employer and a network of specially trained, local pharmacists who have agreed to work cooperatively with your physician, counselor, or other healthcare provider to help you manage your depression.

The Project is designed to improve your health by helping you learn how to better manage your own depression care, facilitating better outcomes with treatment. By successfully managing your depression and maintaining good health, you also will be helping to reduce health care costs for both you and your employer. In fact, you will begin saving money once you are enrolled in the program. **As a participant in the Project ImPACT: *Depression*, your employer has made arrangements for the insurance co-pays for your antidepressant medications to be waived.**

In addition to saving money, you will benefit from the health care services that will be provided by one of the program's specially trained pharmacists. The pharmacist whom you select will act as your personal health care coach and will work with you throughout the time you are enrolled in the program. At the beginning of the program, you and your pharmacist coach will meet at least once a month for the first 3 months. After 3 months, you will meet with your pharmacist once every three months unless more frequent visits are necessary. The pharmacist may schedule periodic telephone "visits" as well.

At these private visits, the pharmacist will:

- Review your treatment plan and establish goals:
- Conduct an initial and ongoing evaluation of your progress;
- Discuss the effectiveness of your medications;
- Suggest other resources that may benefit your progress;
- Answer questions about your condition or treatment plan; and
- Communicate progress to your physician or other health care providers that you designate.

The immediate goal of the initial educational and counseling sessions between you and your coach is to determine some base-line information about your depression, what you already know about depression and how it is being treated, and to develop an overall action plan for your participation in the program.

The program's goal is to have you reach the point where you are sufficiently knowledgeable and skillful in managing your own depression and see improvement in your quality of life. Monitoring and counseling activities for the remainder of the program are devoted to helping you continue progressing in your depression care to achieve optimal benefits from your depression treatment plan. Depression is a treatable

illness, but many patients don't seek or complete treatment. This program is designed to help to support you as you achieve a successful recovery or remission.

If you decide to participate, you will need to complete the necessary enrollment forms included in this packet (for example):

- Consent to participate
- Health questionnaire (confidential)
- Authorization form permitting your physician or other relevant care provider, such as your counselor, to share your medical information with your pharmacist coach

You will not be officially enrolled in Project ImPACT: *Depression* until all the required enrollment forms are completed, and you have received notice of acceptance into the program by Dr. Barry Bunting.

After receiving notice of enrollment, you will also be contacted about an appointment with a pharmacist.

Please call me at 259-5693 or Dr. Barry Bunting at 213-4782 if you have any questions.

Sincerely,

Lynn Hollifield, BSN, RN, COHN-S
Health Services Manager

Project ImPACT: *Depression*

Welcome to Project ImPACT: *Depression* that is being sponsored by your employer, City of Asheville. This project introduces a new type of health care program that has been carefully organized for you and your fellow employees who have depression.

Project ImPACT: *Depression*

What is exciting and different about this new health care program is that the success of the program, in large part, depends on your active participation in your own care. The program is designed to help you maintain good control over your depression by helping you learn how to better self-manage your depression.

Over a 12-month period, you will meet at regularly scheduled times with the health care team -- your physician, pharmacist, and other counselors. You will be a full-fledged member of this team and will help develop a treatment and education support plan that (a) meets your individual health care needs and (b) provides the education and support needed for you to be actively involved in managing your depression.

Each member of the health care team will be responsible for keeping each other informed about actions taken on your behalf, including those responsibilities that you must fulfill. For instance, your pharmacist will keep your physician informed about services provided and their outcomes. Your physician, in turn, will notify your pharmacist when a change in your treatment plan is indicated. Should you be referred to a counselor, they may send progress reports to your pharmacist and physician. And you will be expected to keep the team informed as to your progress or problems that you encounter in self-managing your depression.

Completing your enrollment in Project ImPACT: *Depression*

To complete the enrollment process, you need to fill out and sign a number of forms. Descriptions of each form are provided in the following paragraphs. At the end of each description, you will be directed to the pertinent form that you also need to complete, download, and sign. The completed forms are to be returned to:

Patty Riddle
The Health Education Center
445 Biltmore Avenue, Suite 203
Asheville, NC 28801

Project ImPACT: *Depression*
Consent to Participate Form

By completing this form, you acknowledge that you have been fully informed about the program, including:

1. Your right to confidentiality

In order to assure the confidentiality of the information you provide, a computer generated identification (ID) code will be used to identify you and data resulting from your participation in the program. Further, coded information and data will only be shared with those parties who have a need to know and for whom you give authorization to have access. Parties who will need to have access are trusted health professionals who provide care, pharmacy benefit managers who handle claim forms, and data processing personnel who will aggregate coded data about you and your progress with similarly coded data collected from other patients participating in the same program. Aggregated data will be used to evaluate the overall success of the Project ImPACT:*Depression*. Your name will not be associated with any published results.

2. Employee incentive

As a participant in the program, the co-pays that you are now required to make when purchasing your antidepressant medications will be waived.

3. Clinical assessments and laboratory tests

To assure that your depression and medications are managed appropriately, your physician may conduct certain clinical assessments and laboratory tests. The exact nature of these measurements and tests will be explained to you as you begin participating in the program. The cost of these lab tests will be waived.

4. Risks, inconveniences, and discomforts

As is the case with all health care programs, you are reminded that there are potential risks associated with the treatment of any disease. Specific risks associated with your depression care will be discussed with you as appropriate. Further, because of the time pressure that health care providers work under these days, you may have to arrange your schedule to accommodate that of the health care team. In this regard, it will be expected that you would make every effort to do so (see section on Cancellations and Missed Appointments). Lastly, medical care does have its discomforts. For instance, not too many people look forward to having blood drawn for a laboratory test. You should discuss your individual concerns with your health care team.

5. Right to withdraw.

Since you volunteered to participate in the program, you have the right to withdraw at any time. In the event you find that you are not able to participate in the Project ImPACT: *Depression*, for whatever reason, you should immediately notify the Pharmacy Network Coordinator. His address follows on the next page.

Dr. Barry A. Bunting
Clinical Manager of Pharmacy Department
Mission Hospitals
445 Biltmore Ave. Suite 203
Asheville, NC 28801

6. Authorization to request medical information

Giving permission to enable your pharmacist to obtain confidential information about your depression from your physician, Employee Assistance Network or other health care specialist whom you may be seeing, is important to assure the continuity of your care. You must sign the consent to be able to participate in this program.

7. Selecting your pharmacist and scheduling appointment

During the enrollment process, a pharmacist will be selected for you, taking into consideration both your needs and geographic location.

8. Scheduling appointments

Your pharmacist is to contact you within one week after receiving notification of your enrollment**.** If you are not contacted by the pharmacist within one week, you should notify the Project Coordinator, Dr. Barry Bunting at 213-4762. When your pharmacist calls you, you are to schedule the time for your initial visit.

During your initial visit, the pharmacist will review the Project ImPACT: *Depression* Process of Care with you and answer your questions. Also, it is at this time that you will be asked to complete a brief set of questions that will provide the health care team an initial assessment of depression and quality of life. As indicated above, the results of this initial assessment will be used to develop an overall care plan that will state the specific treatment goals as determined by your physician, as well as the educational and skill training goals set by the entire health care team. The plan will include:

- A schedule of follow up visits at which times the pharmacist will provide indicated counseling, education and skill training;
- A schedule for monitoring adherence to medication therapy and evaluating response and any side effects from medication; and
- A plan for life style changes desired

During the first 3 months of the program, you will meet with your pharmacist approximately two times, with some additional supportive phone sessions to check on your progress. The frequency of visits will vary according to your needs, but will be mutually agreed upon by you and your pharmacist; however, the program requires at least once visit each quarter.

9. Cancellations and Missed Appointments

Except in an emergency situation, you must give 24-hour notice if you are unable to keep a scheduled appointment with the pharmacist. (In the case of an emergency situation, you should notify your pharmacist as soon as possible.) If you do not provide the appropriate notice, you will be contacted by the pharmacist to determine the reason for the missed appointment. If you miss a second appointment

without giving 24-hour notice, you will be contacted by the Project Coordinator to discuss your continuing in the program.

In those instances when the pharmacist may need to schedule, or re-schedule, an appointment with you, the pharmacist will immediately contact you. If you are not available, the pharmacist will leave a message for you. It is very important that you respond to any message promptly. A second failed attempt to contact you will be reported to the Coordinator who will place a call to you. If you fail to respond to the Coordinator, it will be assumed that you do not want to continue and will be notified that you have been dropped from the program.

- -- -

I, ____________________________, understand what will be required of me to become a participant in Project ImPACT: *Depression*. I agree to follow the stated policies and procedures as stated in this document, and understand that my failure to do so may result in my being dropped from the program.

Participant Signature __________________________________ Date ______________
(Or Parent /Guardian)

Project Coordinator's Signature __________________________ Date ______________

AUTHORIZATION OF USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

The privacy law, Health Insurance Portability & accountability Act (HIPAA), protects your individually identifiable health information (protected health information). The privacy law requires you to sign an authorization (or agreement) in order for researchers to be able to use or disclose your protected health information for research purposes in the study entitled Related Aspects of a Wellness Program that Mission Hospitals Sponsors for Employees with Asthma, Diabetes, Hypertension, Hyperlipidemia, Depression. Please read the information below to see if you agree to allow the use of your protected health information for this study.

Who will have access to your protected health information related to your participation in this research study?

- Only the principal investigator, Barry Bunting, Pharm.D, Sharon West, RN, and Patty Riddle, Secretary, and your Care Manager will have access to study information that is identifiable as yours.

What protected health information will be used or disclosed?

- Health information that will be used for this study, but reported anonymously, includes: age, sex, weight, laboratory results, Hemoglobin A1c (where applicable), cholesterol (where applicable), spirometry (where applicable), blood pressure (where applicable) and the responses to disease specific questionnaires that provide medical history, symptoms, list of medications, the questionnaires PHQ-9 and SPS-6 (where applicable) and health related behaviors (nutrition, activity, smoking history). In addition data on the cost of health care for the study group will be tracked and reported.

What will your protected health information be used for?

- This information will be used to determine if an employer sponsored wellness program that provides improved access to medication, education, and frequent follow-up with a care manager will result in clinical improvement and lower overall health care costs.

Who will the researchers share your protected health information with?

- The Mission Hospitals Institutional Review Board.
- Government representatives, such as the Food and Drug Administration and the Office of Human Research Protections when required by law.
- This information may be shared with your physician or health educator (e.g. diabetes educator who is instructing classes you are participating in).
- Individual, but unidentifiable, information will be shared with statisticians for statistical analysis of the study group.
- When laboratory testing is done it will be necessary for laboratory personnel to know who the individuals are that are being tested.
- Information on the group outcomes, but not individual outcomes may be reported in medical and/or pharmaceutical journals.

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization. The researchers agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and federal law.

You do not have to sign this Authorization. If you decide not to sign the Authorization:

- It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You may not be allowed to participate in the research study.

After signing the Authorization, you can change your mind and:

- Not let the researcher disclose or use your protected health information (revoke the Authorization).
- If you revoke the Authorization, you must send a written letter to Barry Bunting to inform him of your decision.
- If you revoke this Authorization, researchers may only use and disclose the protected health information **already** collected for this research study.
- If you revoke this Authorization your protected health information may still be used and disclosed should you have an adverse event (a bad effect).
- If you change your mind and withdraw the Authorization, you may not be allowed to continue to participate in this study.

You may not be allowed to review the information collated for the research until after the study is completed. When the study is over, you will have the right to access the information again.

This Authorization does not have an expiration date.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights in this research study, you should contact the Chairperson of the Mission Hospitals' Institutional Review Board at (828) 213-1105.

I authorize Barry Bunting and his research staff to use and disclose my protected health information for the purposes described above. I also permit my doctors and other health care providers to disclose my protected health information for the purposes described above.

I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed.

_____	_____
Signature of research subject or *Research subject's legal representative	Date
_____	_____
Printed name of research subject or *Research subject's legal representative	Representative's relationship to research subject

*Please explain Representative's Relationship to Patient and include a description of Representative's Authority to act on behalf of Patient:

_____

_____

Project ImPACT: *Depression* Sign-up Form

Personal Information

Name: _____ Gender: [ ] Female [ ] Male

Birth Date: _____

Ethnicity: [ ] African American [ ] Asian [ ] Caucasian [ ] Hispanic [ ] Native American [ ] Pacific Islander [ ] Other

Primary Language:
_____

Highest Grade Completed: [ ] 8th Grade or Less [ ] Some High School
[ ] High School Graduate [ ] Some College
[ ] College Graduate [ ] Post-Graduate Education

Address: _____ Phone: Work: _____

City, State: _____ Home: _____

Zip Code: _____

Primary Care Physician_____

Have you visited a physician within the last year regarding your depression? [ ] Yes [ ] No

If yes, name of physician and date of visit: _____

Have you visited a counselor within the last year regarding your depression? [ ] Yes [ ] No

If yes, name of counselor and date of visit: _____

- - -Information below to be completed by Project ImPACT: Depression Provider - - -

Patient ID: __ __ __ - __ __ __ - __ __ __

Date of Patient Consent: _____

Date of Protected Health Information (PHI) Acknowledgement: _____

Patient Enrollment Date: _____

First Scheduled Appointment Date/Time: _____

Data of Patient Withdrawal from Program: _____

Withdrawal Reason: _____

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

Name: _____ Date: _____

Over the last two weeks, how often have you been bothered by any of the following problems? (Circle your answer)

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3
Trouble falling or staying asleep or sleeping too much	0	1	2	3
Feeling tired or having little energy	0	1	2	3
Poor appetite or overeating	0	1	2	3
Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
Moving or speaking slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3

Add Columns _____ + _____ + _____

Total: _____

(Healthcare Professional: For interpretation of TOTAL please refer to accompanying scoring card.)

If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all Somewhat difficult Very difficult Extremely difficult

Stanford Presenteeism Scale*

(SPS-6)

Directions: Please describe your work experiences **in the past month**. These experiences may be affected by many environmental as well as personal factors, and may change from time to time. For each of the following statements, please check one of the following responses to show your agreement or disagreement with this statement in describing *your* work experiences **in the past month**.

Please use the following scale:

…..I strongly disagree with the statement
…..I somewhat disagree with the statement
…..I am uncertain about my agreement with the statement
…..I somewhat agree with the statement
…..I strongly agree with the statement

	Strongly disagree	Somewhat disagree	Uncertain	Somewhat agree	Strongly agree
Because of my depression the stresses of my job were much harder to handle.	( )	( )	( )	( )	( )
Despite having my depression, I was able to finish hard tasks in my work.	( )	( )	( )	( )	( )
My depression distracted me from taking pleasure in my work.	( )	( )	( )	( )	( )
I felt hopeless about finishing certain work tasks, due to my depression.	( )	( )	( )	( )	( )
At work, I was able to focus on achieving my goals despite my depression.	( )	( )	( )	( )	( )
Despite having my depression, I felt energetic enough to complete all my work.	( )	( )	( )	( )	( )

***PATIENT INFORMATION (Please complete ALL appropriate questions)

SSN_____ DOB_____ GENDER (Please circle one) M F

LAST NAME_____ FIRST NAME_____ MIDDLE NAME_____

MAIDEN NAME_____ RACE_____ NATION/COUNTRY_____

ADDRESS_____ HOME PHONE_____

CITY/STATE/ZIP_____ WORK PHONE_____

EMAIL ADDRESS _____ CELL PHONE _____

DAYTIME PHONE NUMBER: _____MARITAL STATUS (Please circle one) M S W D Separated

EMPLOYER_____ STATUS (Please circle one) Full-time Part-time
(Please state if RETIRED, DISABLED, SELF EMPLOYED or UNEMPLOYED)

PRIMARY PHYSICIAN _____ SPECIALIST _____

***GUARANTOR (To be completed by parent/legal guardian if PATIENT is a MINOR)

LAST NAME_____ FIRST NAME_____ MIDDLE NAME_____

MAIDEN NAME_____ RACE_____ NATION_____

ADDRESS_____ HOME PHONE_____

CITY/STATE/ZIP_____ WORK PHONE_____

MARITAL STATUS (Please circle one) M S W D Separated

EMPLOYER_____ STATUS (Please circle one) Full-time Part-time
(Please state if RETIRED, DISABLED, SELF EMPLOYED or UNEMPLOYED)

***EMERGENCY CONTACT INFORMATION

NAME_____ RELATIONSHIP_____

WORK PHONE_____ HOME PHONE_____

***INSURANCE INFORMATION (State if MCAID, MCARE, OR SELF PAY)
(Complete if primary and policyholder is different from patient OR insurance is secondary)

POLICY HOLDER'S NAME_____ SSN_____

DOB_____ RELATIONSHIP_____ EMPLOYER_____

***To be completed by clinician
INSURANCE CARD COPIES ATTACHED (Please circle one) YES NO (Front and back of cards needed)

MSQP ATTACHED (Please circle one) YES NO N/A *MUST HAVE IN ORDER TO COMPLETE REGISTRATION

DETAILED INFORMATION

1. Which of the following best describes your race/ethnicity? (Check one)
   - ❑ White / Caucasian
   - ❑ Black / African American
   - ❑ Hispanic / Spanish
   - ❑ American Indian / Alaskan Native
   - ❑ Asian / Oriental or Pacific Islander
   - ❑ Other _____

2. What is your primary spoken language? (Check one)
   - ❑ English
   - ❑ Spanish
   - ❑ Other: _____

3. What is the last grade or year of school that you finished? (Check one)
   - ❑ Less than seventh grade
   - ❑ 7^{th} – 11^{th} grade
   - ❑ High school graduate or obtained GED
   - ❑ Some college or vocational training
   - ❑ College graduate
   - ❑ Post-Graduate

4. Do you have any financial concerns? (Check one. If yes, please explain)
   __ No __ Yes: _____

RISK ASSESSMENT AND MEDICAL HISTORY

1. Do you have high blood pressure? __ NO __ YES If yes, when diagnosed?_____

2. Do you have High Cholesterol or Triglycerides? __ NO __ YES If yes, when diagnosed?_____

3. Do you have Diabetes? __ NO __ YES __ Type 1 or __ Type 2 When diagnosed?_____

4. Do you have Asthma? __ NO __ YES If yes, when diagnosed?_____

5. Are you overweight or obese? __ NO __ YES

IF YES to any of the above, how are you currently managing your diagnosis?

__ Diet __ Exercise __ Weight Reduction __ Prescribed Medications __ None __ Other: _____

HEALTH CARE INFORMATION

Name of Primary Doctor: _____

Address: _____ Phone: _____

City/State/Zip: _____ Specialty: _____

When did you last see this doctor? _____

Name of Specialist: _____

Address: _____ Phone: _____

City/State/Zip: _____ Specialty: _____

Please answer YES or NO to the following questions:

Do you smoke cigarettes?……..	Yes	No
If you are female, are you postmenopausal?…….	Yes	No
If you are female, are you on hormone replacement therapy?……..	Yes	No
Do you have a mother or sister who had a heart attack or bypass heart surgery before the age of 65?	Yes	No
Do you have a father or brother who had a heart attack or bypass heart surgery before the age of 55?	Yes	No
Has your doctor ever told you that your heart is enlarged?……	Yes	No
Have you ever had a heart attack?……..	Yes	No
Have you ever had angina, chest pains that your doctor told you were likely related to your heart?…	Yes	No
Have you ever had heart surgery to open up blood vessels in your heart?…….	Yes	No
Do you have heart failure, a condition in which your pump is weakened?……	Yes	No
Have you ever had a stroke or "mild strokes" also known as transient ischemic attacks (TIA)?……..	Yes	No
Do you have kidney disease that you have been told is related to high blood pressure or diabetes?…	Yes	No
Do you have peripheral arterial disease or "hardening of the arteries?"……	Yes	No
Have you ever been told you have eye disease that is related to high blood pressure or diabetes?…..	Yes	No

Please indicate whether you have, or have had any of the following conditions:

Depression……	Yes	No	Kidney Disease……	Yes	No
Arrhythmia (irregular heart beat)	Yes	No	Osteoporosis (thinning bones)	Yes	No
Benign Prostatic Hypertrophy (BPH – enlarged prostate)	Yes	No	Sexual Dysfunction…….. (Problems with sexual performance)	Yes	No
Gout……..	Yes	No	Thyroid Disease……	Yes	No
Lung Disease (COPD)…….	Yes	No	Liver Disease……	Yes	No

Other medical conditions that you have or have had?_____

List any allergies:_____

Do you drink alcohol? Yes No Please indicate quantity and frequency:_____

Do you have a history of using illegal substances?_____

Pharmacy preference / location: _____

Are you currently taking any medications (prescribed, over-the-counter, herbal/homeopathic, home remedies)? Yes No

***Please list all medications that you are currently taking:

NAME OF MEDICATION	STRENGTH	HOW MUCH / HOW OFTEN

(If additional space is needed, please continue on back or attach separate sheet of paper.)